

**IN THE DRAWINGS:**

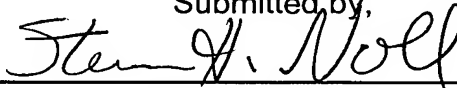
Figures 2 and 6 have amended as shown on the replacement sheets attached hereto.

**REMARKS:**

The present Amendment makes editorial changes in the specification claims and drawings, and adds an Abstract, to conform the present PCT application to the requirements of United States patent practice. Claims 1-17  
5 have been cancelled solely because the amount of strikethroughs and underlining that would have been necessary to confirm those claims to the requirements of 35 U.S.C. §112, second paragraph would have been unduly burdensome and confusing. No change in the claim language between claims 1-17 and the claims presented herein has been made for the purpose  
10 of distinguishing any claims over the teachings of the prior art of record. Accordingly, no change in the claim language is considered by the Applicants as a surrender of any of the subject matter encompassed within the scope of original claims.

Early consideration of the application is therefore respectfully  
15 requested.

Submitted by,



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**A CONGESTIVE HEART FAILURE MONITOR**

***Technical field***

**SPECIFICATION**

**TITLE**

5 **"A CONGESTIVE HEART FAILURE MONITOR"**

**BACKGROUND OF THE INVENTION**

**Field of the Invention**

The present invention relates to a congestive heart failure monitor.

***Background***

10 **Description of the Prior Art**

Electrical stimulation therapy of congestive heart failure is previously known. Thus in ~~US 5-584-868~~ United States Patent No. 5,584,868 a dual-chamber pacemaker designed for treating congestive heart failure (CHF) by changing the AV interval is described and in ~~US 6-223-079-B1~~ United States  
15 Patent No. 6,223,079 a four chamber pacing system for improving cardiac output of CHF patients by controlling pacing to maintain the ventricular mechanical synchronization is disclosed. For providing suitable timing in the latter system impedance sensing in the left heart is used.

Incipient CHF is often present without the patient knowing it. An indicator  
20 for incipient CHF would therefore be of great value since treatment by addition of drugs or electrical stimulation therapy could then be introduced at an early stage of CHF to slow down the progression of CHF. This would prolong the survival of the patient. Such an indicator could also be used to alert the patient or the physician about new conditions so appropriate measures can be taken. The first  
25 sign of a CHF can be seen in the left atrium, for instance in volume changes thereof.

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**SUMMARY OF THE INVENTION**

~~The purpose~~ An object of the present invention is to utilize ~~this~~ the above-  
described knowledge to provide a congestive heart failure monitor for detecting  
CHF at an early stage.

**5 ~~Disclosure of the invention~~**

~~This purpose is obtained by a congestive heart failure monitor according to  
claim 1.~~

The first sign of a CHF can be observed in the left atrium of the heart by  
monitoring its mechanical behavior ~~behaviour~~, like volume changes, as mentioned  
10 above. If the pumping ability of the left ventricle is reduced the volume of the left  
atrium will increase due to the excessive filling of blood. The filling pattern of the  
left atrium can be disturbed due to mitral regurgitation caused by either diastolic or  
systolic dysfunction. The diastolic dysfunction could be a result of prolonged PR  
interval, i.e. the P-wave to QRS interval, or too long an AV interval, resulting in  
15 reversed flow back to the left atrium during diastole as because the mitral valve  
does not close immediately after the atrial contraction. The systolic dysfunction  
could be a result of infarctic areas in the left ventricle, which disturbs the left  
ventricle contraction propagation so that the mitral valve cannot close properly,  
(the papillar muscle get becomes asynchronous), bringing reversed flow back to  
20 the left atrium during systole. The systolic dysfunction in the left ventricle could  
also be a result of bad timing of the right and left ventricle stimulations (e.g.  
septum, innervated at RVOT stimulation, is involved in the left ventricle  
contraction) causing mitral regurgitation and disturbed filling pattern of the left  
atrium. All these conditions ~~results~~ result in a disturbed filling pattern of the left  
25 atrium, which ~~and~~ is one of the first signs of CHF.

A first sign of CHF can thus be observed in the left atrium and since the  
conductivity of blood is different from that of tissue the monitor according to the  
invention ~~comprises~~ has an impedance measuring unit ~~adapted to measure that~~  
measures impedance between at least two electrodes intended to be implanted in

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the patient such that a change in the left atrium volume results in a change in the measured impedance. In this way not only incipient CHF can be detected but also the monitor according to the invention can ~~also~~ be used as a diagnostic tool for studying the progression or regression of CHF for enabling proper treatment of the patient.

~~According to advantageous embodiments~~ In an embodiment of the monitor according to the invention the analyzing ~~means comprise~~ unit includes an averaging ~~means provided to form~~ unit that forms a mean (average) value of the measured impedance during a plurality number of cardiac cycles and the analyzing ~~means are adapted to analyze~~ unit analyzes the mean value to detect CHF. Alternatively, the ~~or said analyzing means comprise~~ unit can include a quotient determining ~~means provided to determine~~ unit that determines the quotient between the impedance minimum and maximum values during a cardiac cycle, and the analyzing ~~means are adapted to analyze~~ unit analyzes the quotient to detect CHF. Preferably the analyzing ~~means are adapted to analyze~~ unit analyzes both the impedance mean value and the quotient to detect CHF. Firstly, even though the impedance changes continuously during the heartbeat, the mean value will decrease when the left atrium volume increases. Secondly, the quotient between the impedance minimum and maximum values will be larger, with increasing blood filling of the left atrium. Accordingly with the present invention an efficient CHF monitor is provided based on the analysis of these two quantities.

~~According to other advantageous embodiments~~ In a further embodiment of the monitor according to the invention the electrodes are designed for implantation in the right and left atria, respectively, or for implantation in the right atrium and left ventricle. In ~~case of~~ an implantable monitor, one of the electrodes can be designed for implantation in the left atrium and the other electrode be formed ~~of~~ by the outer capsule of the monitor, e.g. the pacemaker capsule when the monitor is included in a pacemaker.

Also other combinations of the above mentioned electrodes can be used for the impedance determination.

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The electrodes intended for implantation in the left atrium and the left ventricle are preferably designed for implantation in a coronary vein. For all these alternatives signals corresponding to the blood filling of the left atrium are obtained from the electrodes.

5        ~~According to still other advantageous embodiments~~ In another embodiment  
of the monitor according to the invention the impedance measuring unit ~~comprises~~  
includes a measuring circuit in the form of synchronous demodulator for obtaining  
both the real and imaginary parts of the impedance, and the impedance  
measuring unit is preferably adapted to determine determines the impedance  
10    phase ~~angel~~ angle for detecting and the analysing means ~~is adapted to analyse~~  
analyzing unit analyzes the phase angle for detecting an incipient CHF. Since  
blood is resistive, a high degree of blood filling results in a small phase angle. On  
the contrary, if more heart tissue is present, like as in case of a healthy heart, the  
phase angle will get exhibit a larger negative value.

### 15    ~~**Brief description of the drawings**~~

~~To explain the invention in greater detail embodiments of the monitor  
according to the invention chosen as examples will be described below with  
reference to the enclosed drawings, on which figure 1 illustrates principally the  
impedance measurements performed in one embodiment of the monitor according  
20    to the invention, figure 2 is a simplified illustration of an embodiment of the monitor  
according to the invention, figure 3-5 illustrate alternative ways of performing  
impedance unit of the monitor according to the invention, and figure 7 is a flow  
chart illustrating the signal processing in an embodiment of the monitor according  
to the invention.~~

### 25    ~~**Detailed description of embodiments**~~

## DESCRIPTION OF THE DRAWINGS

Figure 1 schematically illustrates an impedance measurement performed in  
an embodiment of the monitor according to the invention.

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Figure 2 is a schematic illustration of the basic components of the monitor according to the invention.

Figures 3-5 respectively illustrate alternatives for performing impedance measurements in the monitor according to the invention.

5        Figure 7 is a flow chart showing the basic steps in one embodiment of the operation of the monitor according to the invention.

**DESCRIPTION OF THE PREFERRED EMBODIMENTS**

10        Figure 1 illustrates principally measurement of the impedance  $Z$  between the right atrial lead 2 and the coronary sinus lead 4. As the left atrium is dilated due to CHF the impedance  $Z$  will decrease. Also the variation of the impedance between maximum and minimum values will then decrease due to increased wall tension.

15        To secure a safe fixation of the left atrial electrode 6 in the coronary sinus CS or the great cardiac vein it is beneficial to use a screw-in electrode, cf. figure 2. The optimal right atrial RA electrode 2 position is lightly to be in the inter-atrial septum near the coronary sinus ostium, see the electrode tip 10 in figure 3. With the electrodes 6, 8; 10, 11 positioned as shown in figures 2 and 3 the volume of the left atrium is positioned between the electrodes. This enables variations of impedance variations across the left atrium and a high sensitivity to left atrium volume changes.

20

Also, other bipolar electrode measurements set-ups as well as tripolar electrode settings are possible in the monitor according to the invention.

25        The embodiment of the monitor according to the invention shown in figure Figure 2 comprises includes monitor electronics 7 for analysis of the measured impedance for detection of an incipient CHF. An implantation monitor is preferably also provided with telemetry means, not shown in figure Figure 2, for communication with an external programmer and data acquisition device 9.

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Figures 3-5 illustrate quadropolar electrode configurations suitable for use in the monitor according to the invention. In ~~figure~~ Figure 3 the coronary sinus CS lead 12 is positioned on the left atrium and in the ~~figures~~ Figures 4 and 5 the CS lead 14 and 16 respectively is placed on the left ventricle.

5           The method of bio-impedance measurement is not critical in the monitor according to the invention. Figures 3-5 illustrate a technique wherein an electric current  $i(t)$  is supplied between two electrodes and the resulting evoked voltage response  $v(t)$  is detected. In the embodiments shown in figures 3 and 5 the evoked voltage response  $i(t)$  is supplied. Figure 4 shows an embodiment in which  
10       the current  $i(t)$  is supplied between a right atrial electrode 17 and a stimulator can 19, whereas the evoked voltage response is measured between the right atrial electrode 17 and a left ventricular electrode 18 positioned in the coronary sinus.

Figure 6 shows an alternative embodiment of the impedance-measuring unit of the monitor according to the invention in the form of a synchronous  
15       demodulator. Generally the electric current  $i(t)$  is applied to two electrodes 20, 22 and the resulting evoked response is measured between two measurement electrodes 24 and 26. The measured voltage signal is amplified in an amplifier 28. The measured voltage signal is synchronized with the current  $i(t)$  with the aid of a reference signal picked up from the current source 21 and supplied to a  
20       synchronizing ~~means~~ unit in the form of multiplier 30. A low-pass filter 32 is provided to filter the output signal from the multiplier 30. The resulting impedance  $Z_1$  is the given by the expression

$$Z_1 = u_1 / i$$

where  $u_1$  denotes the filtered resulting synchronized output voltage signal.

25           With the impedance measuring circuit shown in ~~figure~~ Figure 6 both the real and the imaginary parts of the impedance are measured and consequently the impedance phase angle is obtained as well ~~too~~.



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As discussed above, at left ventricular dysfunction the left atrium will dilate according to the progress of the disease, because the left ventricle is not able to eject blood into the body and blood will consequently stagnate in the left atrium and pulmonary veins. Left atrium blood pressure will increase as well as left atrium wall tension. The blood volume in the left atrium will also increase while the variation between maximum and minimum volume values will decrease. These phenomena can be determined from the measured impedance.

Figure 7 is a flow chart illustrating an example of an embodiment of the monitor according to the invention analyzing ~~analysing~~ the impedance minimum-maximum quotient and the overall impedance mean value for detecting an early CHF. The impedance raw signal obtained as explained above is pre-filtered, at 34 in the figure Figure 7. The filtering at 34 is performed to remove ~~artefacts~~ artifacts of noise, breathings etc. ~~Mean~~ The mean (average) value of the impedance signal during the last heart cycle is calculated in averaging ~~means~~, at 36, and long time mean value calculation is performed by ~~means of~~ a low pass filter, at 38. The expression "long time" could mean a time of the order of typically 10 minutes in this connection.

At 40 in figure Figure 7 the quotient between the impedance minimum and maximum values is determined. The obtained long term mean value and the quotient between minimum and maximum values are compared with predetermined reference or normal threshold values in comparison means, at 42 in the figure Figure 7. The results of these comparisons are used, at 44, to classify the patient's condition according to predetermined built-in rules.

The processing described above with reference to figure Figure 7 can advantageously be used together with an activity sensor and a posture sensor. The impedance properties can then be calculated during the same conditions for the patient, for instance with the patient in a resting supine position. The processing chain of figure Figure 7 can also preferably contain a memory for saving the time history of calculated parameters for further evaluation in external devices, cf. figure Figure 2.

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Although modifications and changes may be suggested by those skilled in the art, it is the invention of the inventors to embody within the patent warranted hereon all changes and modifications as reasonably and properly come within the scope of their contribution to the art.